UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): April 1, 2020

Soliton, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-38815**	**36-4729076**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

5304 Ashbrook Drive
Houston, Texas 77081
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (844) 705-4866

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

☐

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbols(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	SOLY	The Nasdaq Stock Market

Item 8.01. Other Events

On April 1, 2020, Soliton, Inc. (the "Company") issued a press release providing guidance related to the impact of the coronavirus on its business. A copy of the press release is attached to this report as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Exhibit
99.1	Press release dated April 1, 2020 .

Signature

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SOLITON, INC.

By: /s/ Lori Bisson

Lori Bisson

Executive Vice-President,

Chief Financial Officer

Dated: April 1, 2020

Soliton, Inc.
5304 Ashbrook Drive
Houston, TX 77081

Soliton Announces New Launch Plan of Next Generation Acoustic Shockwave Product Due to COVID-19

- Expects to Include Tattoo and Cellulite in Launch, Subject to FDA Clearance -

April 1, 2020 – Houston, TX –Soliton, Inc., (Nasdaq: SOLY) ("Soliton" or the "Company"), a medical device company with a novel and proprietary platform technology, today provided an update on its business strategy and financial position in light of the current COVID-19 situation.

"In light of the widespread impact of COVID-19, our view of the ideal launch window for our RAP device has naturally changed," commented Christopher Capelli, MD, founder, President and CEO of Soliton. "Clearly, launching an aesthetic device during a national crisis such as the COVID-19 pandemic would be ill-advised. Fortunately for us, though the delay of our limited market launch costs us some time, it has also had a valuable upside. Instead of launching our RAP device focused solely on tattoo removal in mid-2020, we are electing to delay that launch until the aesthetic and financial markets are demonstrating more stability. In the meantime, we will remain highly focused on our regulatory pathway for cellulite reduction. We now believe our initial launch could be timed appropriately to incorporate both tattoo and cellulite indications, subject to FDA clearance of the latter. We are all hopeful that this strategic shift allows sufficient time for our dermatology customers and the market in general to return to some sense of normalcy."

Soliton recently announced that we will be sharing the results from the 12-week follow-up of our pivotal cellulite study through the American Academy of Dermatology's virtual meeting expected to be held in the next 5-7 weeks. It is this data that will provide the clinical basis for our planned regulatory filing. At this time, we do not anticipate a delay in our regulatory plans for the cellulite indication and plan to file our 510(k) in the second quarter of 2020.

As many dermatologist offices are currently closed, we are experiencing follow-up visit cancellations in our ongoing 26-week cellulite assessment and increased difficulty in executing the initiation of further clinical trials at sites around the country. While this will not impact the regulatory pathway for the initial cellulite indication, there is the expectation this will impact the timing of Soliton's planned additional hypertrophic scar proof-of-concept study and the longer-term 26-week follow-up visits in our cellulite pivotal study. Furthermore, it is possible this may extend the time required to file for additional, improved cellulite reduction claims with the FDA and for initial approvals of a hypertrophic scar indication that we may seek in the future.

Given the modification in our timeline and the instability in the financial markets, we have modified our spending plans and now expect our cash on hand to finance our operations to December 2020, assuming that we do not encounter any unforeseen costs or expenses. We will modulate our launch timeline with early indicators of the recovery of the financial and aesthetic markets, with the objective of identifying an appropriate window of opportunity for a successful product debut.

Dr. Capelli concluded, “Despite the turmoil created by COVID-19, Soliton remains focused on executing it’s 2020 milestones related to the regulatory pathway for cellulite and implementing new initiatives to drive continued business momentum. Although our commercialization timeline has been modified and we are facing incremental challenges, we remain committed to our long-term goal of providing our customers with the innovative Rapid Acoustic Pulse technology and generating long-term shareholder value. We appreciate for your continued interest and support in Soliton.”

Join our more than 200K fans here to follow the Company:https://soly-investors.com
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About Soliton, Inc.

Soliton, Inc. is a medical device company with a novel and proprietary platform technology licensed from MD Anderson. The Company's first FDA cleared commercial product will use rapid pulses of acoustic shockwaves as an accessory to lasers for the removal of unwanted tattoos. The Company is based in Houston, Texas, and is actively engaged in bringing the Rapid Acoustic Pulse ("RAP") device to the market. The Company believes this "Soliton" method has the potential to lower tattoo removal costs for patients, while increasing profitability to practitioners, compared to current laser removal methods. Soliton is investigating potential additional capabilities of the RAP technology in clinical and preclinical testing, including the potential to improve the appearance of cellulite by creating mechanical stress at the cellular level and inducing significant collagen growth and the potential to treat keloid and hypertrophic scars by targeting the stiffened environment in the intracellular matrix.

For more information about the Company, please visit: http://www.soliton.com

Forward-Looking Statements

Some of the statements in this release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. Forward-looking statements in this press release include, without limitation, the ability to execute a commercial launch of the RAP device for tattoo removal and cellulite, to execute on our 2020 regulatory plans, and to successfully fund the Company’s operations through December 2020. These statements relate to future events, future expectations, plans and prospects. Although Soliton believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking statements. Soliton has attempted to identify forward-looking statements by terminology including ''believes,'' ''estimates,'' ''anticipates,'' ''expects,'' ''plans,'' ''projects,'' ''intends,'' ''potential,'' ''may,'' ''could,'' ''might,'' ''will,'' ''should,'' ''approximately'' or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including those discussed in our SEC filings, including under the heading ''Item 1A. Risk Factors'' in the Form 10-K for year ended December 31, 2019 we filed with the SEC and updated from time to time in our Form 10-Q filings and in our other public filings with the SEC. Any forward-looking statements contained in this release speak

only as of its date. Soliton undertakes no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

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